REMARKS

In the amendments above, claims 1-4 and 9 have been amended to more clearly recite applicant's invention. No issue of new matter is raised by these amendments. Applicants respectfully request that the Examiner enter and consider this amendment. Upon entry of this amendment, claims 1-4 and 9 as amended will be pending and under examination.

Rejection Under 35 U.S.C. 103

The Examiner rejected claims 1-4 and 9 under 35 U.S.C. 103(a) as obvious over WO 01/12161 ("Martani"). Specifically, the Examiner indicated that even though Martani does not explicitly disclose the claimed particle sizes, friability values, and proportion of insoluble elements, these would have been obvious to one of ordinary skill in the art.

In response, applicant respectfully traverses the Examiner's ground of rejection.

Applicant's invention as now claimed provides a tablet for oral administration that disintegrates quickly in the oral cavity in less than 30 seconds, comprising: i) mannitol of the crystalline form α in a proportion of at least 59.5%; ii)active ingredient in a proportion below or equal to 10%, as a fine powder in which at least 90% in weight of the active ingredient has a particle size less than 100 μm; iii) microcrystalline cellulose in a proportion from 10 to 18%, with an average particle size of approximately 50 μm where at least 99% in weight of microcrystalline cellulose has a particle size below 250 μm; iv) sodium croscarmellose in a proportion from 1 to 4%; and v) a lubricant agent in a proportion from 0.5 to 2% in weight, where, unless specified otherwise, the percentages are expressed in weight of the total weight of the tablet, wherein said tablet has a friability below 0.5%.

Martani discloses a solid dosage form which rapidly dissolves in an aqueous medium, which dosage form comprises an active substance, mannitol, microcrystalline cellulose, croscarmellose Na and a lubricant, wherein such dosage form disintegrates within 30 seconds when taken into the mouth .

Applicant maintains that Martani does not disclose mannitol of the crystalline form α as claimed or any of the claimed ratios of the tablet. Applicant maintains that in the present application, when the term "spray-dried" mannitol is used, it is not referring to a particular method of preparing mannitol but a particular form of mannitol. In the specification as filed on page 6, lines 16-22, it is stated that "[s]pray-dried mannitol is made up fundamentally by the "crystalline form α", unlike the other types of mannitol, which are made of the β form", and that the "disintegrating rate is much faster than that of direct compression mannitol, that of powder mannitol and other related saccharide excipients."

Further, the application as filed discloses that the "spray-dried" mannitol is a critical component of the claimed composition. Particularly, on page 4, lines 7-13, of the present application it is stated that: "[s]urprisingly, the present invention has revealed that by using diluent of high dissolution rate and high compressibility, and limiting the proportion and size of the particle of the insoluble ingredients, mixtures with optimum compressibility can be obtained. These mixtures enable the obtaining of orally disintegrating tablets which disintegrate in the mouth in less than 30 seconds(...)". (Emphasis added)

In addition, as for the component "spray-dried mannitol", the specification discloses on page 7, line 19-page 8, line 26, that "[it] has been established that the compounds of the present invention must contain at least 59.5% of spray-dried mannitol". (Emphasis added)

Applicant maintains that Martani does not disclose or suggest a mannitol of a crystalline form α in the tablet composition present in a quantity of at least 59.5%. Applicant further maintains that this would not have been obvious to one skilled in the art as these finding was unexpected and first disclosed in the present application as stated above.

In addition to the above, page 7, line 34 to page 8, line 8 of the present application discloses "[t]he proportion of microcrystalline cellulose is from 10 to 18% in weight of the total weight of

the tablet (...) and that higher quantities have a negative impact on the palatability of the formula and lower quantities worsen the capacity of the disintegration promoter". In contrast, Martani discloses the quantity of this filler (microcrystalline cellulose) as being at least 30% in weight of the total dosage form (page 11, line 24). Applicant maintains that such a ratio would have a negative impact on its palatability. The same also applies to the ratio of Na croscarmellose.

Moreover, analyzing the parameter of friability, it is shown from the Tables of the present invention that when using "spray-dried mannitol", i.e. a mannitol of a crystalline form α, the friability is always under 0.5% (See page 4, lines 23-24) "The tablets of the invention have a friability of below 0.5%, preferably below 0.2%, as specified by Ph. Eur. 2.9.7." In contrast, Martani discloses in Tables IV and V, Example 5, direct compression dextrose instead of spray-dried mannitol, wherein the friability is increased until 0.84%. A

In view of the amendments made herein and the remarks above, applicant maintains that claims 1-4 and 9 as now amended are not obvious over Martani. Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw this ground of rejection.

Allowance of the claims herein is respectfully requested.

Respectfully submitted,

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